80-680

NO. _____

IN THE

Supreme Court of the United States

OCTOBER TERM, 1980

JACK WERNER,
Petitioner,

v.

THE UPJOHN COMPANY, INC.
AND
RALPH J. CARBO, JR., M.D.,
Respondents.

WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FOURTH CIRCUIT

RESPONDENTS' BRIEF

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QUESTIONS PRESENTED

1. Did the Fourth Circuit correctly hold that the trial court committed reversible error in permitting the plaintiffs to use evidence of a warning issued subsequent to the date of ingestion of defendant's drug by plaintiff for the sole purpose of proving culpable conduct on the part of defendant, after the evidence of the subsequent warning had been offered and admitted solely for the purpose of proving the feasibility of giving the subsequent warning at an earlier date?

2. Did the Fourth Circuit correctly hold that evidence of a subsequent warning after the date of ingestion of defendant's drug by plaintiff was not admissible to show the feasibility of giving the subsequent warning at an earlier date when the feasibility of giving a different warning prior to the date of ingestion of the drug was not controverted by the defendant?

3. Did the Fourth Circuit correctly hold that in a drug liability case, where the product is an unavoidably unsafe product and where the sole issue on the liability of the defendant drug company is the adequacy of the accompanying warning in the package insert, all issues of liability of the defendant involve proof of culpable conduct under the applicable Maryland law, thus precluding admission into evidence of a subsequent warning when the evidence is offered and used by counsel to prove culpable conduct on the part of the defendant?

4. Did the Fourth Circuit correctly hold that in a drug liability case, where the sole issue was the adequacy of the defendant's warning, an answer by the jury on issues that the defendant was guilty of negligence because of the inadequacy of the warning was totally inconsistent with the answer of the jury on strict liability that the warning was not inadequate so as to create totally inconsistent answers to the issues, thus requiring a new trial?

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I. Because the basis of the Fourth Circuit's reversal was a holding that the trial court erred in permitting the plaintiff to use the evidence of the subsequent warning for the sole purpose of proving culpable conduct on the part of the defendant, contrary to the provisions of Rule 407 of the Federal Rules of Evidence, with an alternative holding that the jury's verdicts as to negligence and strict liability were inconsistent, and because the Fourth Circuit's view on the inadmissibility of the subsequent warning on other issues was mere dicta offered solely for guidance upon retrial in the interests of time and judicial economy, there is no important issue of federal law which is ripe for review and settlement by this Court or which is in conflict with the decision of any other circuit. 10

II. The dicta of the Court of Appeals relating to the inadmissibility of the evidence of the subsequent warning, which was given for guidance to the District Court on retrial, is not in conflict with the decision of the Eighth Circuit in *Robbins*, since the two cases are clearly distinguishable and reconcilable both factually and legally. 18

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A. The Fourth Circuit correctly stated that in the context of this drug liability case, where the sole issue is the adequacy of the warning, evidence of a subsequent warning is inadmissible on the issues of strict liability and breach of warranty, and this statement is not in conflict with the Eighth Circuit's decision in *Robbins* 18

B. The Fourth Circuit correctly stated that the evidence of the subsequent warning did not become admissible under Rule 407 merely because the subsequent warning was required by the Food and Drug Administration. This statement is not in conflict with any decisions of other Circuit Courts of Appeals. 22

C. The Fourth Circuit correctly stated that evidence of a subsequent warning is not admissible as evidence of the feasibility of giving a warning different from that actually given, where such feasibility was not in fact controverted by Upjohn. This statement is not in conflict with the decision of the Court of Appeals of another circuit 27

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SUMMARY OF ARGUMENT

I. The Fourth Circuit decision is not in conflict with the decisions of other Federal Courts of Appeals on the applicability, scope, interpretation and administration of Rule 407 of the Federal Rules of Evidence.

A. The Fourth Circuit's reversal of the trial court was based on the improper use of the evidence of the subsequent warning to prove culpable conduct on the part of the defendant contrary to the express provisions of Rule 407 of the Federal Rules of Evidence. This holding is not in conflict with the decisions of other Federal Courts of Appeals.

B. The Fourth Circuit's alternative ground of reversal that the findings of the jury on the issues of negligence and breach of warranty were directly in conflict with the jury's finding on the issue of strict liability was entirely correct, and Petitioner concedes that this issue is not a proper one for review by way of writ of certiorari.

C. The Fourth Circuit's decision on the admissibility of evidence of the subsequent warning on the issues of strict liability, breach of warranty, causation, and feasibility was mere dicta for the guidance of the trial court upon retrial. Accordingly, the "decision" on these issues cannot be in conflict with the decision of the Eighth Circuit. Moreover, because of sharp differences between the facts, procedural issues and the applicability of state law in the decisions of the Fourth Circuit and the Eighth Circuit, there is no direct conflict between the two decisions which would be necessary, desirable or practical for this Court to resolve.

D. The statement of the Fourth Circuit in dicta that evidence of the subsequent warning did not become

admissible under Rule 407 because the warning was required by the Food and Drug Administration is clearly correct and is not in conflict with any decision of another Circuit Court of Appeals.

E. The Fourth Circuit decision that evidence of a subsequent warning is not admissible as evidence of feasibility when feasibility is not controverted involves a clear and settled application of Rule 407, and its determination that the issue of feasibility was not "controverted" was not in conflict with a decision of any other Court of Appeals. Accordingly, the issue is not a proper one for review by way of writ of certiorari.

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RESPONDENTS' BRIEF

STATEMENT OF THE CASE

Because respondent believes that petitioner's statement of the facts of the case beginning at page 4 of petitioner's brief is a biased and inaccurate statement of the facts as set forth in the record extract in the Fourth Circuit and the facts as noted by the Fourth Circuit, respondent believes that it is necessary to restate the facts with appropriate citations to the record extract below. References to "App." refer to the Joint Appendix in the Court of Appeals. References to "T." refer to the transcript of the proceedings in the District Court. References to "P. App." refer to the Appendix in Petitioner's Writ of Certiorari.

A. *Background and Development of Cleocin.*

Before 1965, The Upjohn Company sold a broad-spectrum antibiotic known as Lincocin. Lincocin's primary side effects were intestinal upset, diarrhea, and various forms of colitis with varying degrees of severity (App. 597-98). These side effects had also been reported from the use of most other antibiotics, including penicillin and tetracycline (App. 212, 215, 223-24). Because Lincocin had a higher reported incidence of gastric side effects than some of the other antibiotics, Upjohn developed Cleocin,[1] a synthetic analog of Lincocin (App. 201), in approximately 1965.

After laboratory testing for efficacy, Cleocin was extensively tested in animals and humans before it was approved for marketing by the Food and Drug Administration (FDA) in 1970 (App. 383-84). This research indicated that Cleocin had a much lower incidence of diarrhea and gastric upset than Lincocin (Plaintiff's Ex. 12, App. 498). In clinical studies on 5500 patients, there was not one reported incident of colitis (App. 404-05).

Cleocin was approved by the FDA for marketing in 1970 with a "package insert" containing its indications for use and statements of adverse reactions (Plaintiff's Ex. 56A, App. 564). A package insert is the literature distributed with each package of a drug; it contains the recommended indications for use and

[1] Cleocin is the trade name for the generic Clindamycin.

warnings of known or possible side effects. This insert must be approved by the FDA and published with any announcement or advertisement for the drug, and it must accompany any literature concerning the drug distributed to physicians (App. 386-87). The package insert also appears verbatim in the *Physicians Desk Reference* (PDR), a yearly publication containing such inserts for all prescription drugs on the market.

Cleocin was found to be an important and extremely effective broad-spectrum antibiotic (App. 345). It was widely used as an alternative to penicillin for persons who were penicillin allergic and for patients who could not tolerate other antibiotics (App. 345). It was used throughout the country and extensively in the Maryland medical community (App. 353).

As the use of Cleocin became more widespread, Upjohn began to receive reports of diarrhea and colitis as adverse reactions (App. 387-88). Upjohn thoroughly investigated these reports and forwarded them to the FDA (App. 388). The reports resulted in a series of changes in the warnings accompanying Cleocin (App. 387). The series of changes up to 1973 generally stengthened the warnings and included additional indications of reported side effects (Plaintiff's Ex. 56A). All changes were approved by the FDA (App. 387).

In 1973, a number of articles appeared in medical journals noting clinical cases of colitis following ingestion of Cleocin (Plaintiff's Exs. 10, 58). Each article was reported to the FDA (App. 388-89). The true incidence of diarrhea, colitis and acute colitis was difficult to determine because the only basis for accumulating incidence data after these articles began to appear was the adverse reaction reports submitted by the medical community to Upjohn (see Upjohn Ex. 11, App. 604-05). Based on well accepted indices prepared by independent agencies, Upjohn estimated that, up to August 1974, 15.7 million persons had been treated with Cleocin, yet Upjohn had received only 209 reports of colitis (App. 401-02).

B. *Dr. Tedesco's Study*

Because of the reports of colitis in both the literature and the adverse reaction reports, Upjohn in 1973, initiated four studies of Cleocin patients (App. 389), one of which was a prospective study by Dr. Francis Joseph Tedesco at Barnes

Hospital in St. Louis (App. 180). The final results of Tedesco's study were sent to Upjohn in late April of 1974 (App. 185; Plaintiff's Ex. 31, App. 500), although interim reports had been sent in late 1973 (App. 499). Upjohn forwarded Tedesco's reports to the FDA at the various stages of completion (App. 416).

Dr. Tedesco, who testified as the plaintiff's expert, found diarrhea in 21 percent of the patients using Cleocin in Barnes Hospital and, on sigmoidoscopic examination, signs of pseudomembranous colitis (PMC) in 10 percent (App. 183, 500). PMC was generally known at the time to be an extremely serious disease with a mortality rate between 50 and 75 percent (App. 218). While Dr. Tedesco made these findings in a patient population of only 200, he was the first physician in making such a study to sigmoidoscope most of the Cleocin patients who developed diarrhea (T. 396). Most significantly, however, Tedesco's study revealed that Cleocin-induced PMC was not the kind of serious disease process that had previously been associated with PMC, but rather was one that was benign and self-limiting (App. 501). All of Tesesco's patients in the study recovered (App. 221), and Dr. Tedesco found that if PMC were diagnosed and treated promptly, no serious complications would be likely to develop (App. 222), with recovery expected in most instances in four to seven days (App. 501). Thus, Tedesco agreed that the incidence of "serious" colitis, in relation to his study, depended upon how one defined "serious" (App. 189), since there was no clearly understood definition of that term in the medical community (App. 226). Even Tedesco defined "serious colitis" as only those cases where that patients had been in the hospital for weeks suffering from severe medical complications (App. 226). Tedesco's 10 percent incidence finding was admittedly, therefore, not an indication that 10 percent of the population would contract "serious" colitis from the ingestion of Cleocin.

C. *The Kalamazoo Meeting*

In November 1974, following the publication of Dr. Tedesco's study (App. 441), Upjohn invited several professors of medicine to attend a meeting at Upjohn's offices in

Kalamazoo (App. 440). These persons were all chiefs of infectious disease divisions of their respective medical schools (App. 440). Dr. Frank Calia of the University of Maryland was one of these experts (App. 429, 440), and he subsequently testified on behalf of Upjohn.

The purpose of the meeting was twofold: to educate the experts as to the data sent to Upjohn concerning PMC and to obtain recommendations from these experts with respect to designing further incidence studies of Cleocin's side effects (App. 441). All adverse reaction reports, including all serious colitis and mortality cases, were made available to and were reviewed by the experts (App. 441). As related by Dr. Calia, Upjohn "took us into a room, laid [the data] on the table, . . . and the company officials left and left us alone" (App. 441). A number of recommendations for further study resulted from that meeting (App. 441). Dr. Calia subsequently testified that, in his opinion, the 1974 package insert was entirely adequate to inform a reasonably competent physician of the adverse reactions and side effects from the use of Cleocin (App. 435).

D. *The 1974 Package Insert and "Dear Doctor" Letter*

In the summer of 1974, following the receipt of Tedesco's study, Upjohn and the FDA corresponded and met frequently concerning possible revision of the Cleocin package insert (Upjohn's Exs. 8 - 14, App. 599-630). These contacts resulted in Upjohn changing the warnings for Cleocin, with the approval of the FDA, in August 1974 (Upjohn's Exs. 13 and 14, App. 622-23). The new package insert instituted a "black box" warning, which read as follows:

WARNING

Severe and persistent diarrhea, which may be accompanied by blood and mucus, and which may be associated with changes in large bowel mucosa diagnosed as "pesudomembranous colitis," has been reported in asoociation with the administration of Cleocin HC1 (clindamycin HC1 hydrate).

When significant diarrhea occurs (usually more than 5 bowel movements daily), the drug should be discontinued

or, if necessary, continued only with close observation of the patient (large bowel endoscopy has been recommended). Mild cases of colitis may respond to drug discontinuance alone. Moderate to severe cases should be managed promptly with fluid, electrolyte and protein supplementation as indicated. Antiperistaltic agents – opiates, meperidine, and diphenoxylate and atropine may prolong and/or worsen the condition. Systemic corticoids and corticoid retention enemas may help relieve the colitis. Other causes of colitis should also be considered.

Note: Diarrhea has been observed to begin up to several weeks following cessation of therapy with Cleocin HCl. The physician must be alert to this possibility.

Three additional changes had been suggested by some FDA personnel. First, some wanted a specific warning that deaths had resulted from PMC (T. 921; Plaintiff's Exhibit 37). Other persons at the FDA (T. 925; Plaintiff's Exhibit 38) and at Upjohn thought this totally unnecessary, since the disease process "pseudomembranous colitis" noted in the new warning was still generally known to be a serious complication and one that had a very high mortality rate, according to all of the medical experts who testified at trial (App. 217-18). Second, the FDA suggested language that Cleocin was known to cause colitis "and rarely pseudomembranous colitis." (App. 391-92; Upjohn Ex. 8, App. 599). Upjohn replied that it would not be accurate to add "and rarely pseudomembranous colitis" in view of the conflicting incidence figures dramatized by Dr. Tedesco's recent study (App. 393-94); Upjohn Ex. 10, App. 601). Finally, some FDA personnel suggested language recommending that Cleocin not be used for "minor" or "trivial" infections, an addition Upjohn opposed because such a statement was applicable to antibiotics generally (Plaintiff's Ex. 37, App. 504, 507). None of these changes were required by the FDA in 1974.

Coincident with the FDA approval of the 1974 black-box warning for Cleocin, Upjohn, with the approval of the FDA, prepared a "Dear Doctor" letter, which was mailed with the new package insert to every physician in the United States. It was stipulated that the "Dear Doctor" letter containing the new adverse reaction warnings and the new package inserts was

mailed to Dr. Carbo on August 17, 1974 (App. 136-37). Carbo could not say that he did not receive the material and could not deny that it was received (App. 301). In October 1974, the new warning was also published in Supplement B to the 1974 PDR. Supplement B was admittedly available in Dr. Carbo's office by December 1974 (App. 299-300), when he prescribed Cleocin for the plaintiff.

The August 1974 package insert and the "Dear Doctor" letter dated August 16, 1974 (Plaintiff's Ex. 38, App. 514), contained substantially all of the recommendations suggested by Dr. Tedesco in his report (App. 216-17, 240), except that Tedesco's specific incidence data were not published. Upjohn felt that Tedesco's findings could not be accepted, without further study, as indicating the true incidence of serious colitis. Tedesco's study had a tiny population (200 patients) as contrasted with the 15.7 million people that Upjohn knew had ingested Cleocin as of 1974, and from which Upjohn had received reports of only 209 cases of colitis (App. 402). Further, the antibiotic-induced PMC found by Tedesco could not be equated with "serious" colitis (App. 435) because most of Tedesco's patients were not seriously ill (App. 400), all recovered, and Tedesco himself described the disease as benign and self-limiting (App. 501). Accordingly, Upjohn was reluctant to generalize from Tedesco's limited data (App. 393; Upjohn Ex. 10, App. 601). Meanwhile, Upjohn continued existing studies (App. 389), continued to finance further Tedesco studies (App. 389), and initiated others (App. 389), all in an effort to verify the Tedesco findings. These later studies found much lower incidences of Cleocin-related diarrhea and PMC than Tedesco had found (T. 494-511, 515-18, 626-28, 801-03, 816-20, 856-57) and even today the true incidence of Cleocin-related PMC and serious colitis is hotly in dispute (App. 434-35).

In preparing its "Dear Doctor" letter in August of 1974, Upjohn treated every case of colitis reported to Upjohn as a case of "serious colitis" and, using these figures as the best available incidence data at that time, reported an incidence of one in 50,000 to one in 100,000 cases of serious colitis among persons taking the drug (App. 402-05). This incidence did not purport to be that for Cleocin-related PMC, but only for

"serious" colitis resulting from the drug. The "Dear Doctor" letter indicated that the incidence data was difficult to project at that time and discussed the factors that made obtaining a true incidence figure difficult (App. 515). Like the August 1974 package insert, the "Dear Doctor" letter was approved by the FDA before publication (App. 400).

After the revision of the package insert in August of 1974, Upjohn decided to discontinue promotion of the oral form of Cleocin (App. 407). This decision was based largely on the fact that Upjohn had been advised that there would be a meeting of the FDA Infectious Disease Advisory Committee sometime in the fall of 1974, where there would be a full discussion of Cleocin-induced colitis and PMC; that both the FDA and Upjohn would have the benefit of the expertise of the Advisory Committee after the meeting took place; and that the meeting would probably result in further revisions of the package insert and cautionary warnings (App. 407, 423). Upjohn was specifically informed by the FDA that the 1974 warnings were probably only "interim" pending the Advisory Committee meeting (T. 923; Plaintiff's Ex. 37, App. 511). Thus, Upjohn decided to limit promotion of the drug until the Advisory Committee met. The Advisory Committee did not meet until January of 1975 (App. 406).

E. *Dr. Carbo's Prescription of Cleocin for Plaintiff*

On December 10, 1974, Dr. Carbo, an opthalmologist who used antibiotics only five to ten times per year (App. 288), prescribed Cleocin for treatment of a chalazion on the plaintiff's eyelid (App. 287).

At this time, the revised warning was contained in the October 1974 supplement to the *Physicians Desk Reference* (PDR) to which Dr. Carbo subscribed, and the Supplement was admittedly received and available in his office (App. 299-300). Dr. Carbo had not read the 1974 warning in the PDR supplement or the "Dear Doctor" letter when he prescribed the drug to the plaintiff (App. 302), even though it was Dr. Carbo's regular practice, with respect to each of the very few drugs he used, to retain all "Dear Doctor" letters and attach them to the most current PDR for reference (App. 301). Thus, in prescribing Cleocin for the plaintiff, Dr. Carbo, by his choice alone,

relied totally on the information contained in the outdated 1973 package insert and on his own experience with the drug (App. 306). Dr. Carbo himself conceded that to review the 1974 warning in the PDR Supplement would have taken "only a minute" (App. 327).

Because Carbo had not read the "Dear Doctor" letter, he was not aware of Upjohn's estimate contained therein for incidence of "serious" colitis of 1 in 50,000 to 1 in 100,000 (App. 331). Thus, nothing in the "Dear Doctor" letter influenced Carbo's judgment to prescribe Cleocin for the plaintiff (App. 302).

F. *The 1975 Change in the Package Insert*

In January of 1975, the FDA Infectious Disease Advisory Committee met in Washington, D.C. As a result of those meetings and further dialogue between the FDA and Upjohn, a revised Cleocin package insert was prepared, approved by the FDA and published in March of 1975 (T. 944-45; Plaintiff's Exhibit 56-B, App. 581). It contained new warnings concerning the risk of colitis and PMC and revised indications for use of the drug. The major additions adopted by the 1975 warning were (1) a warning that antibiotic-induced colitis "may end fatally," and (2) an indication that Cleocin should be used only for "serious" infections. Similar package insert language had been the subject of discussion between Upjohn and the FDA in the summer of 1974 prior to the August 1974 change in the package insert. Upjohn moved *in limine* to exclude all reference to the 1975 warning, based on Rule 407 of the Federal Rules of Evidence (App. 43). The motion was denied (App. 53), and the 1975 warning was subsequently admitted into evidence, over Upjohn's objection (App. 138), for the alleged purpose of showing the "feasibility" of Upjohn providing the 1975 precautionary measures in 1974 (App. 465). However, the 1975 warning was used repeatedly by the plaintiff in the examination of expert witnesses and in argument to prove what plaintiff contended the 1974 warning "should have" said (*e.g.*, App. 140, 145-46, 174, 202, 454-55).

G. *The Testimony of the Experts*

Plaintiff's principal expert witness was Dr. Tedesco, who had conducted the 1974 Upjohn-sponsored study discussed above. After explaining his study and its results, he criticized the statements in the "Dear Doctor" letter as being nonrepresentative of the true incidence of serious colitis (App. 190). Tedesco conceded, however, that this judgment depended on how "serious" was defined (App. 189) and that if "serious" meant "resulting in death," then Upjohn's incidence figures would be realistic (App. 226). Tedesco never contended that his incidence figures should have been published. Tedesco further conceded that the 1974 revision substantially followed his recommendations for disclosure to the medical profession (App. 216-17, 240) and that the August 1974 package insert warned against the very side effects experienced by the plaintiff (App. 240-41, 217). Dr. Tedesco commented generally upon numerous other post-Tedesco studies which showed a much lower incidence of diarrhea and colitis (T. 494-511, 515-18, 516-28). The sum and substance of Dr. Tedesco's criticism of the 1974 warning was specifically that a warning of possible fatality should have been included and generally that the March 1975 warning should have been given in August 1974 (App. 202).

Dr. Richard Hornick, Professor Medicine and head of the Division of Infectious Diseases at the University of Maryland Medical School (App. 340-41) and Dr. Frank Calia, Professor of Medicine and Infectious Diseases at the University of Maryland Medical School (T. 1022) and Chief of Medicine at the Veteran's Administration Hospital (T. 1023), testified as expert witnesses on behalf of Upjohn. Dr. Hornick had previously served as a member of the FDA Antibiotic Advisory Board (App. 366). Both Dr. Calia and Dr. Hornick were thoroughly familiar with the drug, its uses, and adverse reactions (App. 341; T. 1024-26). Dr. Hornick and Dr. Calia each stated that the 1974 package insert was adequate to advise a reasonably competent physican of the adverse reactions and side effects from the use of Cleocin (T. 349-50, 435). Calia further testified that he believed it proper not to disclose the results of Dr. Tedesco's study either in the package insert

or in the "Dear Doctor" letter in August of 1974; Calia felt that such action would have been misleading (App. 437-38). Dr. Hornick discussed the existence of the other available data at the time of Tedesco's April 1974 report, which data indicated a much lower incidence of colitis and PMC than Tedesco found (App. 305-51, 375). Hornick also discussed numerous post-Tedesco studies that similarly reported much lower incidence figures (T. 801-02, 803, 816-20, 856-57). Hornick noted the wide variance in incidence figures between different geographical locations and different hospital environments (App. 351). Hornick personally knew of only one case of PMC after widespread use of Cleocin at University Hospital in Baltimore and knew of only one other in the entire metropolitan Baltimore community (App. 352). Hornick was also familiar with recent studies done by Dr. Francis Milligan at Johns Hopkins Hospital in Baltimore, which found a PMC incidence of only 0.3 percent (App. 353-54, 356-57, 816-17). Dr. Calia testified that serious colitis caused by Cleocin is a rare phenomenon with an incidence much lower than the incidence of pseudomembranous colitis (App. 435).

H. *Closing Argument, Instructions, Verdict, and Post-Trial Proceedings*

Following the denial of Upjohn's motion for directed verdict at the close of the evidence (App. 451), the case was argued to the jury and submitted under the court's instructions by way of special interrogatories (App. 51-52). Defendants excepted to the court's liability and damages instructions.

The jury requested further instruction on the strict liability issues (App. 491), and shortly after receiving further instructions the jury returned a special verdict for plaintiff on the issues of negligence and breach of warranty, but found in favor of Upjohn on the strict liability issue (App. 51). Damages of $400,000 were assessed (App. 52).

ARGUMENT

I.

BECAUSE THE BASIS OF THE FOURTH CIRCUIT'S REVERSAL WAS A HOLDING THAT THE

TRIAL COURT ERRED IN PERMITTING THE PLAINTIFF TO USE THE EVIDENCE OF THE SUBSEQUENT WARNING FOR THE SOLE PURPOSE OF PROVING CULPABLE CONDUCT ON THE PART OF THE DEFENDANT, CONTRARY TO THE PROVISIONS OF RULE 407 OF THE FEDERAL RULES OF EVIDENCE, WITH AN ALTERNATIVE HOLDING THAT THE JURY'S VERDICTS AS TO NEGLIGENCE AND STRICT LIABILITY WERE INCONSISTENT, AND BECAUSE THE FOURTH CIRCUIT'S VIEW ON THE INADMISSIBILITY OF THE SUBSEQUENT WARNING ON OTHER ISSUES WAS MERE DICTA OFFERED SOLELY FOR GUIDANCE UPON RETRIAL IN THE INTERESTS OF TIME AND JUDICIAL ECONOMY, THERE IS NO IMPORTANT ISSUE OF FEDERAL LAW WHICH IS RIPE FOR REVIEW AND SETTLEMENT BY THIS COURT OR WHICH IS IN CONFLICT WITH THE DECISION OF ANY OTHER CIRCUIT.

In his Petition for Writ of Certiorari, the plaintiff broadly asserts that the Fourth Circuit made rulings concerning the admissibility of evidence of subsequent remedial measures which the plaintiff contends are in conflict with decisions of other federal circuit courts of appeals. The plaintiff buries in his petition, however, the primary issue which had been raised by the defendant in the Court of Appeals and which formed the real basis for the Fourth Circuit's reversal and remand for a new trial: Whether the trial court erred in permitting the plaintiff to use the evidence of the subsequent warning for the sole purpose of proving negligence and culpable conduct on the part of the defendant, contrary to the express provisions of Rule 407 of the Federal Rules of Evidence, particularly where the evidence had been offered and admitted solely for the purpose of proving the feasibility of giving the warning at an earlier date. Plaintiff also conveniently ignores the express doubts indicated in the Fourth Circuit's opinion as to whether the issue of the admissibility of the evidence for other purposes was even properly before it because the issue was not raised at

trial and the further express indication of the Fourth Circuit that it only examined that issue "because this case must be tried again," obviously in the interests of time and judicial economy. Under such circumstances the plaintiff is simply wrong in his conclusion that an important, unsettled question of federal law was decided and that this "decision" was in conflict with any other circuit. Rather, the Fourth Circuit's ruling in this case was narrowly based upon the application of the clear and unambiguous language of Rule 407, which prohibits the admission and use of evidence of subsequent remedial measures to prove negligence or culpable conduct on the part of the defendant.

The holding of the Fourth Circuit that a new trial was required because the trial court improperly permitted the plaintiff to use evidence of the subsequent warning to prove culpable conduct, contrary to the provisions of Rule 407 of the Federal Rules of Evidence, was succinctly stated in the written opinion of the Court of Appeals:

> Federal Rule of Evidence 407, which enacts the common law rule excluding subsequent remedial measures to prove negligence, does, however, permit evidence of subsequent remedial measures to be used to prove the feasibility of such measures, but only if feasibility is controverted by the defendant. But, despite the judge's limiting instruction on this point it is clear that the 1975 warning was used by the plaintiff to prove negligence. The warning was mentioned several times during the course of the trial when expert witnesses were asked whether the information in the 1975 warning should have been included in the 1974 warning if that information had been available to Upjohn at the time the 1974 warning was given. This use of the warning has no conceivable connection to feasibility. The plaintiff's expert witnesses were asked time after time whether Upjohn "should have" included the information in the 1975 warning in the 1974 warning. The obvious inference is that if Upjohn should have used the subsequent warning earlier, then it was negligent for failing to do what it "should have" done. This use of the 1975

> warning clearly was impermissible and constitutes reversible error. *Columbia & Puget Sound R. Co. v. Hawthorne*, 144 U.S. 202 (1892).

(P. App. 6a-7a.) The holding of the Fourth Circuit, therefore, was much more limited in its effect than represented by plaintiff. There can be no question that the true basis of the Fourth Circuit's ruling was that regardless of any arguments advanced by plaintiff in support of the admissibility into evidence of the subsequent warning, it was the use of such evidence by plaintiff's counsel to prove negligence and culpable conduct on the part of defendant which required reversal of the judgment of the District Court. In short, it is clear from the opinion of the Fourth Circuit that reversal would have been required solely because of the improper use of the evidence by plaintiff's counsel.

The Fourth Circuit's decision was also based on a clear alternative ground, which the plaintiff concedes is not a proper issue for review by way of certiorari. The Fourth Circuit stated:

> One further point deserves specific mention for it serves as an alternative ground for a new trial for Upjohn. It is claimed that the verdict for Upjohn on the issue of strict liability is inconsistent with the verdict against Upjohn on the issue of negligence. We agree. The effect of the jury verdict on negligence was to find that Upjohn failed to use due care to give an adequate warning of the propensities of the drug marketed, and, in the same breath, the verdict on strict liability found that the drug marketed with such an inadequate warning was not unreasonably dangerous. The verdicts in the context of this failure to warn case involving prescription drugs are obviously inconsistent and cannot stand. The same may be said of the verdict against Upjohn so far as it may be upon an implied warranty, for the only evidence that the drug was not reasonably fit concerned the warning.

(P. App. 19a-20a.) This holding is undoubtedly correct.

By special verdict on the negligence issue, the jury found that the defendant Upjohn failed to exercise reasonable care to give an adequate warning to the medical profession of the risks of Cleocin and that this failure was a proximate cause of

the plaintiff's injury. The jury further found, however, that Upjohn did not market or sell Cleocin in a defective condition unreasonably dangerous to the consumer proximately resulting in injury to the plaintiff, and under the Court's instructions, this finding necessarily indicates that the jury found the warning adequate or that any inadequate warning was not a proximate cause of the plaintiff's injury. Thus, the special finding in favor of Upjohn on the strict liability issue is directly contrary to the jury's findings against Upjohn as to negligence. This inconsistency necessitated the granting of a new trial by the Fourth Circuit.

The law is settled that the inconsistency of a jury's verdict is grounds for a new trial under Rule 59(a) of the Federal Rules of Civil Procedure. *6A Moore's Federal Practice* ¶ 59.08[4], at 59-141 (2d ed. 1979). Indeed, where the verdicts in the same case are patently inconsistent, indicating that the jury was confused or had abused its power, there is no discretion in the trial court on the Rule 59 motion—a new trial must be granted. *Hopkins v. Coen*, 431 F.2d 1055, 1059 (6th Cir. 1970); *Global Van Lines v. Nebeker*, 541 F.2d 865, 868 (10th Cir. 1976); *Wood v. Holiday Inns, Inc.*, 508 F.2d 167, 175 (5th Cir. 1975). Moreover, the court has a positive duty to grant the new trial where the verdict manifests that the jury has not followed the Court's instructions. *Magill v. Westinghouse Elec. Corp.*, 464 F.2d 294, 301 (3rd Cir. 1972); *Reisberg v. Walters*, 111 F.2d 595, 597 (6th Cir. 1940); *6A Moore's Federal Practice* ¶ 59.08[4], at 59-139 (2d ed. 1979).

In this case, under the law and under the trial court's instructions, the verdicts of the jury are inconsistent and irreconcilable. Setting aside the narrow question of whether there is any difference between negligence and strict liability in tort with respect to the duty of a prescription drug manufacturer, it is clear that if a difference does exist under general products liability law, the manufacturer's duty in strict liability is broader than that in negligence, since theoretically one could market a defective product, but not be negligent in doing so. *See Chestnut v. Ford Motor Co.*, 445 F.2d 967, 969 (4th Cir. 1971). A finding in favor of the manufacturer on strict liability therefore necessitates the same disposition on negligence, since

implicit in such a finding is the absence of a defect or unreasonably dangerous condition in the product proximately causing the plaintiff's injury. *See Caplaco One, Inc. v. Amerex Corp.*, 435 F. Supp. 1116, 1120 (E.D. Mo. 1977). Thus, a verdict in favor of a manufacturer in strict liability, but against the manufacturer in negligence, is logically inconsistent. *Halvorson v. American Hoist & Derrick Co.*, 240 N.W.2d 303, 307 (Minn. 1976).

The same reasoning obviously applies under the law relating to a drug manufacturer's duty to warn. Under the law, if a drug manufacturer negligently fails to warn of the side effects of a drug of which the manufacturer knows or should know, it is liable also in strict liability for the failure to warn, since the absence of the adequate warning renders the drug "defective and unreasonably dangerous" within the meaning of Section 402A of the *Restatement*. On the other hand, if a drug manufacturer is not liable in strict liability, i.e., the drug was not defective because an adequate warning was given, *Restatement (Second) of Torts* §402A, comment *k*, then neither can the manufacturer be held negligent for selling an unavoidably unsafe drug, but with an adequate warning. *See Basko v. Sterling Drug, Inc.*, 416 F.2d 417, 425-427 (2nd Cir. 1969). Thus, under the law, the jury's finding in favor of Upjohn on the strict liability issue–*which necessarily included a determination that Upjohn's warning was adequate or that any inadequacy was not a proximate cause of the injury*–was hopelessly inconsistent with the jury's verdict for the plaintiff on the negligence issue, with the specific finding that the warning was *not* adequate and that such negligence *was* a proximate cause of the plaintiff's injury.

The Fourth Circuit was thus correct in basing its reversal on this clear alternative ground, which Petitioner concedes is not a proper certiorari issue.

In his Petition for Writ of Certiorari, however, the plaintiff represents to this Court that the real reason for the Fourth Circuit's reversal was its ruling that, in the context of this case, the evidence of the subsequent warning would not be admissible on the issues of strict liability, breach of warranty, causation, and feasibility. From the written opinion of the Fourth Circuit itself, however, it is clear that its rulings in this regard were not

grounds for reversal, but rather, were merely dicta to offer guidance to the District Court on retrial, in the interests of time and judicial economy. Indeed, the Fourth Circuit expressed its doubts that those questions were even before it, since they were not squarely raised below.[2] Specifically, the Fourth Circuit stated:

> Alternatively, plaintiff argues that even if the 1975 warning was not admissible to show feasibility it was admissible on other grounds. It is arguable that this question is not directly before us on appeal because the 1975 warning was in fact used to prove negligence, and *thus the fact that the evidence might have been admissible on some other ground not raised at trial should not prevent reversal and a new trial. Especially because this case must be tried again*, and we do not believe that the 1975 warning was admissible, we examine plaintiff's other arguments for admitting the evidence.

(P. App. 11a, emphasis added.) Thus, the main issue pressed by the plaintiff in his Petition for Writ of Certiorari was dealt with by way of dicta by the Court of Appeals below and was not the basis for its decision. Rather, the issue was discussed by the Fourth Circuit only for guidance on retrial in the interests of time and judicial economy, and was not even squarely before the Fourth Circuit for decision. Accordingly, the main issue presented by the plaintiff to this Court is not ripe for review, and the Fourth Circuit therefore has not actually decided an important question of federal law which should be decided or settled by this Court.

Moreover, because the actual basis for the Fourth Circuit's ruling is other than as plaintiff contends, it is apparent that the decision of the Fourth Circuit cannot be squarely in

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[2]In its instructions, the trial court limited the use of the evidence of the subsequent warning to the issue of feasibility (P. App. 6a). Plaintiffs did not except to this instruction or even request an instruction broadening the use of the evidence to the issues of strict liability, warranty, or causation. Accordingly, plaintiffs were not in any position to raise other grounds for admissibility on appeal.

conflict with the decision of the Eighth Circuit in *Robbins v. Farmers Union Grain Terminal Ass'n*, 552 F.2d 788 (8th Cir. 1977). First, unlike the Fourth Circuit's opinion in this case, the *Robbins* court did not base its decision on the improper use of the evidence of subsequent remedial measures at trial, and specifically found it unnecessary to do so. *Id.* at 792. Second, in *Robbins*, the trial court gave no limiting instruction, and the defendant did not request one, nor did it object to the court's failure to give a limiting instruction. The opposite is true in this case. Finally, the issue of the use of the evidence for strict liability purposes was squarely before the *Robbins* court, since the lower court had ruled it admissible for that purpose. *Id.* In this case, however, it was not before the Fourth Circuit, because the plaintiff simply failed to preserve the point during trial by not objecting to the trial court's instruction limiting the use of the evidence to the issue of feasibility only.

In short, the Fourth Circuit's decision below was based on two clear alternative grounds: (1) that a new trial was required because the trial court erred in permitting the plaintiff to use the evidence of the subsequent warning to show negligence and culpable conduct of the defendant; and (2) that the jury verdicts in favor of the defendant on the strict liability issue and against the defendant on the negligence issue are irreconcilably inconsistent. The first ground is a settled application of Rule 407 under its clear and unambiguous provisions. The second ground is concededly not a proper issue for review by this Court by way of certiorari. Accordingly, this case presents no important issue of unsettled federal law actually decided by the Fourth Circuit which is necessary or desirable for this Court to review. That the Fourth Circuit addressed the issues raised in plaintiff's Petition for purposes of guidance to the trial court on retrial in the interests of time and judicial economy does not present a ripe or justiciable issue for decision by this Court, particularly in light of the fact that plaintiff clearly failed at trial to preserve his issues for appellate review, even by the Court of Appeals. These factors show equally that there has been no actual decision by the Fourth Circuit of important federal law which conflicts with the decisions of the Court of Appeals of any other circuit, since the alternative bases for the Fourth Circuit's

opinion was never addressed in the *Robbins* decision of the Eighth Circuit, even by way of dicta. Accordingly, the plaintiff's contentions in support of his petition for review of the case by way of certiorari are totally without merit, and the Petition for Writ of Certiorari should therefore be denied.

II.

THE DICTA OF THE COURT OF APPEALS RELATING TO THE INADMISSIBILITY OF THE EVIDENCE OF THE SUBSEQUENT WARNING, WHICH WAS GIVEN FOR GUIDANCE TO THE DISTRICT COURT ON RETRIAL, IS NOT IN CONFLICT WITH THE DECISION OF THE EIGHTH CIRCUIT IN *ROBBINS*, SINCE THE TWO CASES ARE CLEARLY DISTINGUISHABLE AND RECONCILABLE BOTH FACTUALLY AND LEGALLY.

A. *The Fourth Circuit correctly stated that in the context of this drug liability case, where the sole issue is the adequacy of the warning, evidence of a subsequent warning is inadmissible on the issues of strict liability and breach of warranty, and this statement is not in conflict with the Eighth Circuit's decision in Robbins.*

The Fourth Circuit correctly stated that in a drug liability case where the sole issue is the adequacy of the warning of side effects because the drug is an unavoidably unsafe product within the meaning of comment *k* of Section 402A of the *Restatement (Second) of Torts*, issues of negligence, strict liability and breach of warranty are the same, and all involve proof of culpable conduct. Thus, in the context of this case, where the adequacy of the warning is the sole issue, evidence of the subsequent warning is not admissible on the strict liability and warranty issues because such proof would be in violation of the express provision in Rule 407 that "evidence of the subsequent measures is not admissible to prove negligence or culpable conduct in connection with the event." The Fourth

Circuit noted that the rule itself does not speak in terms to the question of whether the evidence should come in to prove strict liability or breach or warranty (App. 13a). In the context of the issues raised by the record in this case in the trial court, however, no distinction could be made between the issues of negligence, strict liability, or breach of warranty (App. 15a-17a). The court expressly noted:

> . . .Under a negligence theory the issue is whether the defendant exercised due care in formulating and updating the warning, while under a strict liability theory the issue is whether the lack of a proper warning made the product unreasonably dangerous. Though phrased differently the issue under either theory is essentially the same: was the warning adequate?. . .
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> Any remaining distinction in theories disappears when a failure to warn case involves an unavoidably dangerous drug which the product in this case admittedly was. The Restatement of Torts (2d) §402A, comment k makes it clear that a drug manufacturer is not to be held strictly liable for injuries caused by an unavoidably dangerous new drug if the warning is adequate. The standard for liability under strict liability and negligence is essentially the same. *Chambers, supra* at 381.
>
> Since the issue under either theory is the same, a decision which admits evidence of subsequent remedial measures on a strict liability theory in a failure to warn case involving an unavoidably dangerous drug would promote substance over form and subvert the policy behind excluding evidence of subsequent remedial measures. We decline the invitation to follow the other courts which may have so held, and prefer the reasoning of *Chambers v. G. D. Searle & Co.*, 441 F.Supp. 377 (D.Md. 1975), exactly to the point here, and *Smith v. E. R. Squibb & Sons, Inc.*, 273 N.E.2d 476 (Mich. 1979), very nearly so.

(P. App. 16a-17a.)

The effect of the Fourth Circuit's language is that where the issue in the trial court focuses entirely on the reasonableness

of the defendant's conduct in giving a warning in light of knowledge existing at the time of the ingestion of the drug, the analysis of the defendant's conduct by the trier of the fact to establish a violation of a duty owed by defendant to the plaintiff necessarily involves proof of that type of culpable conduct expressly forbidden by Rule 407. The opinion does not foreclose admission into evidence of subsequent remedial measures when offered to prove that the product was unreasonably dangerous and defective under a different kind of strict liability case.

The Eighth Circuit's decision in *Robbins* is not in conflict with the Fourth Circuit's opinion here, because the two cases arose in a vastly different factual context and involved the application of conflicting local law. Even under the Federal Rules of Evidence, a federal court sitting in diversity must first determine whether the proffered evidence is material and legally relevant to the substantive issues of state law to be decided. The state law of strict liability involved in *Robbins*, however, differed substantially from the law of Maryland involved in this case. The *Robbins* case involved the adequacy of warnings and instructions for use accompanying the defendant's cattle feed, which cannot be deemed an "unavoidably unsafe" product within the meaning of comment *k* of Section 402A of the *Restatement*. The Eighth Circuit specifically noted that knowledge of the defendant was *not* an element of a strict liability action under the state law there applicable; rather, that the law imputed knowledge to a manufacturer of the harmful character of its product, whether it actually knows of it or not. *Id.* at 794-95, n.15. Thus, the *Robbins* court held that the local strict liability law did not involve "culpable conduct," and thus, the subsequent warning was relevant to show that the product was dangerous and defective because of an inadequate warning and to show that safer design or warning was feasible. *Id.* The substantive strict liability law applicable to the instant case, however, is contrary to that in *Robbins*. Unlike *Robbins*, the instant action is a drug liability case involving an unavoidably unsafe product within the meaning of comment *k* of Section 402A of the *Restatement*. Under that comment, the theory of strict liability as far as drugs are concerned is essentially the same as the theory of negligence, where the sole

question is the adequacy of the warnings accompanying the drug. *Chambers v. G.D. Searle & Co.*, 441 F. Supp. 377, 380 (D. Md. 1975), *aff'd*, 567 F.2d 269 (4th Cir. 1977). Negligence principles are therefore fully applicable even to the strict liability claim. *Id.*; Merrill, *Compensation for Prescription Drug Injuries*, 59 Va. L. Rev. 1, 31 (1973); *see Nolan v. Dillon*, 261 Md. 516, 523, 276 A.2d 36, 40 (1971). Unlike *Robbins*, the knowledge of the manufacturer in this case was clearly relevant to the strict liability issues.

Moreover, an "adequacy of warning" case is nothing more than one involving "defective design," to which strict liability is not applicable under Maryland law, but rather traditional principles of negligence apply, *Frericks v. General Motors Corp.*, 274 Md. 288, 336 A.2d 118 (1975), except under limited circumstances where the conditions are so obviously dangerous that, whether caused by errors in design or manufacture, they can never be said to involve a reasonable risk. *Phipps v. General Motors Corp.*, 278 Md. 337, 345, 363 A.2d 955, 959 (1976). This principle is fully applicable to drug cases under Maryland law. *Nolan v. Dillon*, 261 Md. 516, 276 A.2d 36 (1971). Maryland law thus provides that a manufacturer is not to be held liable unless, after a traditional balancing of "utility-risk" as is done in negligence cases, the trier of facts finds that the conduct of the manufacturer was indeed unreasonable. As contrasted to the law of the jurisdiction applicable in the *Robbins* case, Maryland law on strict liability in an "adequacy of warning" case *does* involve all of the elements of culpable conduct recognized in *Chambers v. G.D. Searle & Co., supra*.

In short, the decisions of the Eighth Circuit in *Robbins* and of the Fourth Circuit in this case are quite distinguishable solely on the basis of the local law of strict liability, which clearly affect each court's application of Rule 407 of the Federal Rules of Evidence. Indeed, the two decisions can be reconciled on this basis. While the evidence may have been admissible in *Robbins* because it was relevant to establish a "defect" in the product in the absence of "culpable conduct" on the part of the manufacturer, it could not be so admitted on the strict liability issue in this case, because Maryland law does not permit recovery in a drug case involving adequacy of warning on the

basis of strict liability unless the plaintiff shows some antecedent knowledge on the part of the manufacturer which would render its conduct unreasonable and culpable under the same standards applicable in negligence cases. How the Fourth Circuit would rule under the *Robbins* factual circumstances with different principles of local law to be applied is unknown and cannot be derived from its opinion in this case. Simply stated, any "conflict" in the two cases was mandated only by the difference in local law of products liability which was applied by each court under entirely different and distinct factual circumstances.

Accordingly, contrary to the plaintiff's contention in his Petition, the Fourth Circuit's opinion in this case is not in conflict with any other circuit on the applicability, scope, interpretation and administration of Rule 407. Because of the different applicable local law and the distinct factual circumstances in each case, the two decisions do not present such a conflict as to require this Court to attempt to achieve a uniform result in the two distinct factual and legal settings. Indeed, because of the great factual and legal differences in the two cases, any such attempt to establish a hard-and-fast, uniform rule would be undesirable and contrary to the purpose of the Federal Rules of Evidence to promote growth and development of the law of evidence and to secure fairness in the administration of justice on a case-by-case basis. *See* Fed. R. Evid. 102.

B. *The Fourth Circuit correctly stated that the evidence of the subsequent warning did not become admissible under Rule 407 merely because the subsequent warning was required by the Food and Drug Administration. This statement is not in conflict with any decisions of other Circuit Courts of Appeals.*

In asserting that the Fourth Circuit erroneously found that the evidence of the subsequent warning was not admissible merely because it was required by the FDA, plaintiff ignores the particular and compelling policy reasons for inadmissibility noted by the Fourth Circuit under the FDA regulatory scheme, which were not involved or discussed in the other cases cited by the plaintiff in his Petition. Plaintiff also overlooks the principle that Rule 407 governs admissibility of *admissions by conduct*,

which obviously cannot apply where the particular action taken was not voluntary, but rather was required by a third-party, since the theory of an "admission" is no longer available. *McCormick On Evidence* §275, at 667 n. 17 (2d ed. 1972).

The Fourth Circuit succinctly responded to the plaintiff's argument that the evidence was admissible merely because the FDA required the subsequent warning:

> Plaintiff's final argument on the admissibility of the 1975 warning is that it was required by the FDA, and that since defendant Upjohn had no choice in the matter, the policy behind Rule 407 would not be served by excluding the evidence. While this argument may have a surface plausibility, we do not believe the evidence should be admitted for this reason. First, when a third party has required the change the relevance of the evidence is one more step removed from the central issue in the case, the adequacy of the warning at the time the product was marketed. When a third party makes a subsequent change the inference is removed not only in time but in who made the change. This is especially true in the case at bar since the FDA itself approved the 1974 warning at the time it was first used. Thus, it would appear that any separate relevance of the FDA's actions with regard to the 1975 warning is overridden by the fact that the FDA approved the 1974 warning as well.
>
> Furthermore, plaintiff's argument overlooks the dual responsibility for preparing warnings for prescription drugs. The FDA can require that a warning be changed, but this does not tell the whole story. In addition to its broad regulatory sanctions it is clear that it also relies on voluntary compliance and compromise in determining the content of warnings and advertising for prescription drugs. See Dixon, Drug Product Liability §5.05. This cooperative aspect of prescription drug regulation is apparent in the correspondence between Upjohn and FDA in the case at bar in arriving at warnings and their changes. Furthermore, FDA regulations allow drug companies to change the labels

> and warnings accompanying their products without prior FDA approval where new side effects are discovered by the company. 21 C.F.R. §314.8(d)-(e).
>
> The. . .regulations demonstrate that plaintiff's argument is without merit. If subsequent warnings are admitted to prove antecedent negligence simply because FDA required or might have required the change, then drug companies may be discouraged from taking early action on their own and from participating fully in voluntary compliance procedures. Thus, we think that the FDA's regulatory power should not be read as in conflict with the protective policy of Rule 407. The FDA's regulations and policies encourage early unilateral action by the drug companies to improve their warnings, and Rule 407 promotes the same goal. We therefore hold that FDA regulations in the area of drug labeling do not require a new exception to Rule 407. Indeed, to find such an exception would subvert the policy goals of both Rule 407 and FDA Regulations 314.8(d)-(e).

(P. App. 17a-19a.)

It was because of the factual context in which the subsequent warning was given in this case in cooperation with the FDA, and that all of the matters addressed in a subsequent warning were the subject of discussion between Upjohn and the FDA in the summer of 1974 prior to the August 1974 change in the package insert, that the admission of the evidence was precluded. This is not a case where the regulatory agency based on information not revealed by defendant required a subsequent warning, but it is simply a case where the regulatory agency, in cooperation with the manufacturer, approved a different warning after the date of the event giving rise to the lawsuit not based on any new information not previously disclosed by the defendant but only as a result of a meeting of the FDA Infectious Disease Advisory Committee and further dialogue between the FDA and Upjohn (T. 944-45; Plaintiff's Exhibit 56B, App. 581).

These particular facts and policy considerations were simply not present in the cases cited by the plaintiff which

purportedly are in conflict with the Fourth Circuit's opinion in this case, and in two of the cases, the pronouncements were merely dicta. In *Rozier v. Ford Motor Co.*, 573 F.2d 1332 (5th Cir. 1978), the admissibility of a "Trend Cost Estimate" was at issue. The Fifth Circuit expressly found that the document was *not* prepared by the defendant *after* the "event" in question, and that the document was not a "remedial measure taken." *Id.* at 1343. The Fifth Circuit also expressly found the document admissible on other issues. *Id.* The Fifth Circuit's statements in connection with Rule 407 were therefore pure dicta. In *Farner v. Paccar, Inc.*, 562 F.2d 518 (8th Cir. 1977), the second case cited by the plaintiff, the Eighth Circuit's statements with respect to the safety measures carried out by a third-party were stated as dicta in a footnote and were far from a direct holding that such evidence would be admissible in *all* cases. *Id.* at 528, n.20 ("We also note that the rule against admission of subsequent remedial measures in negligence cases *may* not apply in any event since the corrective measures were not carried out by the defendant.") (emphasis added). Finally, *Lolie v. Ohio Brass Co.*, 502 F.2d 741 (7th Cir. 1974), the third case cited by plaintiff, was decided prior to the effective date of the Federal Rules and merely held without discussion that remedial measures taken at the direction of the state mine inspector were admissible. *Lolie* was not a drug liability case, and the compelling policy considerations under the FDA regulatory scheme were not discussed or involved.

In short, an analysis of the cases cited by the plaintiff in "conflict" with the dicta of the Fourth Circuit in this case reveals no actual decision in which the same issues were raised or in which actual conflicting rulings were made. At best, the cases provide merely conflicting dicta in widely different factual contexts, but offer no direct conflict which is necessary or desirable for this Court to resolve. To do so would require this Court to lay down broad, hard-and-fast rules which would prevent the flexibility and liberality that the Federal Rules of Evidence are designed to achieve on a case-by-case basis.

Regardless of any alleged conflict among the circuits on this issue, however, the plaintiff misconceives the applicability of Rule 407 in the context of remedial actions taken by third parties. Rule 407 is based upon the theory that certain types

of conduct on the part of the defendant may be used as implied "admissions." Advisory Committee's Note Rule 407; 2 *Weinstein's Evidence* ¶407 [01], at 407-5 (1980). Rule 407 does not set forth a broad rule of admissibility of such conduct when offered for purposes other than negligence or culpable conduct. Rather, the rule merely states that it "does not require exclusion" of the subsequent remedial measures when offered for other purposes. Nevertheless, the evidence must be relevant and admissible for some purpose before any question as to the applicability of Rule 407 is presented, and the general rules governing relevancy apply to subsequent remedial measures made or ordered by a third party. 2 *Weinstein's Evidence, supra* at 407-7; Fed. R. Evid. 401-3.

When evidence of subsequent remedial measures made or required by third parties is offered, however, there no longer exists a theory that such evidence is admissible as an "admission" of a party, because an admission by the *defendant's* conduct as to a relevant issue can no longer be implied. *McCormick on Evidence* §275, at 667 n. 17 (2d ed. 1972). Rather, when the remedial measures are made or ordered by a third party, such evidence is actually a hearsay statement of opinion by such third party, who is not present in court for cross-examination. *Id.*; see Fed. R. Evid. 701, 801 (c) - (d).

Clearly, the plaintiff in this case could not have used as evidence an unsworn, out-of-court statement from a FDA official stating that in his opinion, a stronger warning should have been given. Such evidence would not only constitute hearsay, but also inadmissible opinion evidence. Yet, the effect of the admission of the subsequent warning required by the FDA would be the same, for it is clearly an implied, unsworn statement of opinion of a FDA official that the later warning should have been given earlier. Admission of such an implied statement would deprive the defendant of the right to cross-examine that statement, and, particularly with reference to this case, to point out that the same individual had previously believed, based upon the same state of his knowledge, that the earlier warning was adequate. It was clearly not the intent of Rule 407 to open the door to such hearsay opinion evidence. Rather, the design of the rule is to exclude on policy grounds certain evidence that would otherwise satisfy the Federal Rules'

requirements of relevancy, competency and admissibility. Under such circumstances, the fact that the FDA required the subsequent warning renders the evidence inadmissible for any purpose and hardly brings the evidence within an "exception" to Rule 407.

C. *The Fourth Circuit correctly stated that evidence of a subsequent warning is not admissible as evidence of the feasibility of giving a warning different from that actually given, where such feasibility was not in fact controverted by Upjohn. This statement is not in conflict with the decision of the Court of Appeals of another circuit.*

Although petitioner strives mightily to indicate that feasibility was in fact controverted, the opinion of the Fourth Circuit puts any such argument to rest by its succinct observations in the opinion:

> Plaintiff's position is further weakened by the fact that the feasibility of giving the 1975 warning in 1974 simply was not in issue in the case. As stated above, Rule 407 does allow evidence of subsequent remedial measures to be used to prove the feasibility of such measures, but only if feasibility is controverted by the defendant. The Advisory Committee Notes to Rule 407 state in terms that "unless a genuine issue" of feasibility is present the exception should not apply. The plaintiff contends that the issue of feasibility was controverted sufficiently to invoke the exception. His first argument is that no concession was made by defendant on this issue. However, it is clear from the face of the rule that an affirmative concession is not required. Rather, feasibility is not in issue unless controverted by the defendant.
>
> In an effort to show a controverted issue of feasibility the plaintiff points to two statements Upjohn made to the FDA during negotiations on what was to be the exact content of the 1974 warning in which Upjohn purportedly argued that a stronger warning would be "misleading" or

would have a "potential for much harm." When these statements are examined in context it is apparent that plaintiff's argument is without merit. The first statement was made in reply to the FDA's suggestion that the phrase "and more rarely in PMC" be added to the 1974 warning. Upjohn's reply suggested a warning which stated: "Antibiotic associated 'PMC' can occur." In rejecting use of the word "rarely" Upjohn noted that Dr. Tedesco's study indicated that incidence was higher than "rarely" and that in general Upjohn preferred to avoid terms such as "rarely" or "infrequently", "since there is a distinct possibility of misleading". Thus, it appears that Upjohn's proposed exclusion of the word "rarely" strengthened, rather than weakened, the FDA's proposed warning, and certainly had nothing to do with controverting the feasibility of a stronger warning.

The second example cited by plaintiff arose out of an FDA request that the 1974 package insert include a warning that Cleocin not be used for minor infections. Such a warning ultimately was adopted in substance in the 1975 warning. In objecting to the FDA's proposal Upjohn stated that "there is no precise definition of minor or trivial infections and the physician is adequately guided by the limitation of the approved INDICATIONS. Such a statement has a potential for much harm and little or no benefit." The above quoted statement does not controvert the feasibility of writing a warning that Cleocin not be used for minor infections. It merely questions the necessity of such a warning. This distinction points up the basic position of Upjohn in this case that the 1974 warning was adequate. Upjohn does not argue that it could not have written a stronger warning, it argues that the 1974 warning was adequate given the knowledge it had at that time. This defense simply does not raise an issue of feasibility.

Thus, plaintiff's efforts to expand the feasibility exception must fail. Since feasibility was not in issue in the case the evidence should have been excluded. See Advisory Committee Notes to Rule 407.

(P. App. 9a-10a.)

Thus, the Fourth Circuit, after a thorough and conscientious review of the evidence as recorded in the record extract, expressly found that feasibility was not in issue in this case. The express language of Rule 407 states that evidence of a subsequent warning to prove feasibility is not admissible when feasibility is not controverted by the defendant. Accordingly, the evidence was not admissible on the feasibility issue.

The plaintiff claims, however, that this Court should review this dicta by the Fourth Circuit because it again "conflicts" with the Eighth Circuit's decision in *Robbins v. Farmers Union Grain Terminal Ass'n*, 552 F.2d 788 (8th Cir. 1977). This contention is without merit. In *Robbins*, the Eighth Circuit specifically did not reach the question because it found that the evidence was admissible on other grounds and that the defendant had failed to request any limiting instruction or object to the trial court's failure to give a limiting instruction. *Id.* at 792. Indeed, the Eighth Circuit even questioned the procedure used by the trial court in forcing the defendant either formally to admit feasibility or allow the evidence of the subsequent warning. *Id.* n. 8. Thus, there is simply no conflict between the dicta of the Eighth Circuit in *Robbins* and the dicta of the Fourth Circuit in this case that even approaches the satisfaction of any standard for desirable or necessary review by this Court. Under such circumstances, the Petition for Writ of Certiorari should be denied.

CONCLUSION

Because the opinion of the Fourth Circuit correctly addresses the issues in the factual context of this case, as demonstrated by the record from the United States District Court, the Petition for Writ of Certiorari should be denied. A perceived conflict between the opinion of the Fourth Circuit and the opinion of the Eighth Circuit Court of Appeals in *Robbins* is an erroneous perception by petitioner, and the difference in the results and dicta of the two cases is one that derives from a vastly different factual and legal context in which the evidence of subsequent warnings was offered. The Fourth Circuit correctly based its opinion on a judgment that

regardless of the admissibility *vel non* of the evidence of the subsequent warning, its improper use by counsel below required reversal, a ruling that involved a settled application of Rule 407 under its clear and unambiguous provisions. The Fourth Circuit also correctly based its reversal upon a judgment that the verdicts of the jury were irreconcilably inconsistent, which Petitioner concedes is not a proper certiorari issue. For these reasons, the Petition for Writ of Certiorari should be denied, and the judgment of the Court of Appeals for the Fourth Circuit should be left undisturbed.

Respectfully submitted,

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